REMARKS

Summary of the Office Action

Claims 1-60 are pending in this application.

Claims 32-60 have been withdrawn as directed to a non-elected invention.

Claims 1-31 have been rejected under 35 U.S.C. §112, second paragraph, as indefinite.

Claims 1-10, 15, 16 and 20-31 have been rejected under 103(a) as obvious over Caro (WO 00/32241) in view of Von Oepen (WO 00/13611).

Claims 11-14 have been rejected under 103(a) as obvious over above combination further in view of Lukic et al. (5,709,703).

Claim 17 has been rejected under 103(a) as obvious over Caro (WO 00/32241) in view of Von Oepen (WO 00/13611) and further in view of Kula (EP 1042997).

Claims 18 and 19 have been rejected under 103(a) as obvious over Caro (WO 00/32241) in view of Von Oepen (WO 00/13611) and further in view of Kitakoa et al. (6,174,326).

Applicants' Response

Applicants have amended claim 1 to clarify that the stent of the present invention is configure for implantation ***within*** a body lumen and has a degree of curvature that is custom-formed ex vivo to substantially match the curvature of the body lumen as determined by mapping. Specifically, claim 1 now recites that the "***degree of curvature of the longitudinal axis of the stent is obtained by mapping the curvature of the body lumen and then custom-forming the tubular member ex-vivo so that the degree of curvature of the stent substantially matches***

the curvature of the body lumen". Support for this recitation is provided in the specification at page 6, lines 8-22 and page 22, line 4, through page 23, line 2.

By contrast, neither Caro nor Boylan suggest custom-forming an internal stent ex vivo to impose a curvature on the stent that substantially matches the pre-mapped curvature of the body lumen. Although originally-filed claims 4 and 10 were directed to some of the concepts incorporated and expanded upon in amended claim 1, the Office action provides no rationale for those rejections. Based upon study of that reference, applicants submit that ex vivo custom-forming of an internally implantable stent based upon pre-mapping of the specific body lumen would not have been apparent to one of ordinary skill based on the disclosure of Caro.

On the contrary, the internal stents disclosed in Caro comprise flexible helical or wire mesh structures that are designed to conform to the vessel in vivo (see, e.g., Caro at page 7, second and third full paragraphs). There is no discussion anywhere in Caro of first mapping the curvature of the body lumen, and then ex vivo custom-forming an internally implantable stent to match that mapped curvature.

Likewise, the stents described in Boylan are superelastic mesh structures that may be given a preset curvature during manufacture so as to conform to the vessel shape after implantation (see, e.g., col. 3, line 54 to col. 4, line 11). Boylan contains ***no*** teaching or suggestion that the preset curvature ***should be based on pre-mapping of the body lumen***.

New claim 61 is directed to a stent that is selected from amongst a plurality of stents having different predetermined degrees of curvature, wherein the selection is based upon matching the predetermined curvature of the stent to

a curvature of the body lumen determined by mapping. More specifically, claim 61 recites a stent comprising "***a tubular member selected from amongst a plurality of tubular members, each one of the plurality of tubular members having a longitudinal axis with a predetermined degree of curvature… wherein the tubular member is determined by mapping the curvature of the body lumen and then selecting the tubular member having a predetermined degree of curvature that most closely matches the curvature of the body lumen.***" Support for this recitation is provided in the specification at page 23, lines 3-23 and page 25, lines 14-19.

Applicant submits that neither Caro nor Boylan suggest selecting a stent for implantation within a vessel by matching the pre-mapped curvature of the body lumen to a predetermined curvature of one of a plurality of stents. Although originally-filed claims 8 and 10 were directed to some of the concepts incorporated and expanded upon in new independent claim 61, the Office action provides no rationale for those rejections. Applicants submit that selection of a stent from amongst a plurality of stents based on pre-mapping of the specific body lumen is not taught or suggested by either Caro or Boylan.

As discussed above, the internal stents of Caro are flexible helical or wire mesh structures that are designed to conform to the vessel in vivo. Likewise, the stents described in Boylan are superelastic mesh structures that are given a preset curvature during manufacture so as to conform to the vessel shape after implantation (see, e.g., col. 3, line 54 to col. 4, line 11), but that reference contains ***no*** teaching or suggestion that the preset curvature ***should be based on pre-mapping of the body lumen***.

Applicants submit that dependent claims 2-31 and 62-85, which depend from independent claims 1 and 61, respectively, patentably distinguish over the prior art of record for at least the same reasons as claims 1 and 61.

CONCLUSION

In view of the foregoing, applicants respectfully submit that the application is in condition for allowance. An early and favorable action is earnestly requested.

Respectfully submitted,

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